USDA

United States Department of Agriculture

March 26, 2019

Richard Keigwin
Director, Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW,
Washington, DC 20460-0001

Re: USDA Comments on the Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated With Systemic Insecticides; EPA-HQ-OPP-2018-0805.

Dear Mr. Keigwin:

USDA is writing in response to EPA's seeking of public comments for a petition requesting that the Agency either initiate a rulemaking or issue a formal Agency interpretation for handing and planting seeds treated with systemic insecticides. Petitioners are represented by the Center for Food Safety, who believe that the Agency has improperly applied the Treated Article Exemption in exempting these products from registration and labeling requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). To be clear, while the actual seed being treated is exempt from registration, the active ingredients applied to the seed (if they are insecticides, fungicides, nematicides, growth regulators, etc.) are regulated under FIFRA and are subject to regulation under FIFRA, FFDCA, and FQPA.

It is USDA's position that the petitioners do not have a valid claim. USDA is unable to locate any case that supports the petitioners' false notion that seeds should be differentiated from plants. However, in a prior 2016 lawsuit initiated by many of the same petitioners submitting the petition at hand (Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016)—it was alleged that EPA failed to protect pollinators by authorities it has under FIFRA. The purported failure stems from 2013 guidance the agency issued that allows pesticide-treated seeds to be exempt from regulation as pesticides. The guidance allows the use of treated seeds (which in this case the concern is seed coated with neonicotinoids), i.e., on page 7 of the guidance:

> "[t]reated seed (and any resulting dust-off from treated seed) may be exempted from registration under FIFRA as a treated article and as such its planting is not considered a "pesticide use." [40 C.F.R. § 152.25(a)]. However, if the inspector suspects or has reason to believe a treated seed is subject to registration (i.e., the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated. (See the FIFRA Inspection Manual for further considerations.)"

Office of Pest Management Policy
1400 Independence Avenue, S.W.
Washington, D.C. 20250-0314

The federal district court ruled that the language from EPA's guidance is not subject to legal review as it is not a final notice. The following outlines further germane sections from Anderson:

> In Anderson, the Petitioners emphasized a footnote in Heckler v. Chaney, 470 U.S. 821 (1985). Anderson, 2016 WL 6834215, at 10. The Heckler decision, which applied 5 U.S. Section 701(a)(2), held that in situations where an agency "refus[es] to take enforcement steps...the presumption is that judicial review is not available" because "an agency's decision not to prosecute or enforce...is a decision generally committed to an agency's absolute discretion." Id. The exception to this general rule—i.e., the "Heckler exception" plaintiffs rely on—is in a footnote to the aforementioned analysis, wherein Heckler stated the Court "express[ed] no opinion" on whether an agency's decision to "consciously and expressly adopt [ ] a general policy that is so extreme as to amount to an abdication of its statutory responsibilities" would similarly be "unreviewable under § 701(a)(2)." Id.
>
> Anderson found the Petitioner's argument to had a fundamental flaw. That is, the "Heckler exception" requires an agency decision to "consciously and expressly" adopt a general policy. Id. at 11. Anderson found that EPA's 2013 Guidance expressly contemplated potential enforcement of FIFRA requirements as to pesticide-treated seeds. Id. Anderson found that the 2013 Guidance directly contradicted plaintiffs' allegations of a "policy of non-enforcement" and "abdication of duties." Id. Anderson, further noted that "even assuming for the sake of argument that a blanket-exemption policy as to pesticide-treated seeds would constitute an abdication of the EPA's responsibilities under FIFRA as to such seeds, there is no basis for finding the EPA 'consciously and expressly adopted a general policy' abdicating its statutory responsibilities here." Id.
>
> Most importantly, the Petitioners lost their motion to compel "completion and supplementation" of the administrative record and to conduct limited discovery. Id. at 12. Because of a prior order, the EPA submitted under seal for in camera review "documents that relate to the development of the guidance that are not a part of the administrative record, including pre-decisional and deliberative documents." Id. The court found nothing that would weigh in plaintiffs' favor on the issue of "whether the agency should proceed by guidance versus some other procedure" or "whether the guidance would constitute final agency action." Id. Nor did any document submitted for in camera review support application of the "Heckler exception" to this case. Id.

Based on the current Petition and the Anderson case, it is USDA's opinion that this Petition is a roundabout manner to compel the EPA to supplement the administrative record in advance the Petitioner's next attempt to file a lawsuit concerning treated seeds.

Further, interpretations of this assumed exemption are embodied in other EPA regulations. For example, the Pesticide Registration (PR) Notice 2000-1, pertaining to the Applicability of the Treated Articles Exemption to Antimicrobial Pesticides, clarifies that "section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles of or substances treated with, or containing a pesticide, if: (1) the incorporated pesticide is registered for use in or on the article or substance, and; (2) the sole purpose of the treatment is to protect the article or substance itself." Although this PR Notice applies to antimicrobials, the interpretation should

hold for conventional pesticides as well. Another example can be found in 40 CFR, § 174.3., which for the purposes of Plant-Incorporated Protectants defines a plant as, "for plant-incorporated protectants, means an organism classified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. This includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants." Note that a Plant-Incorporated Protectant is defined as a "pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof." From these definitions, it is gathered that EPA considers seeds to be plants and it is USDA's opinion that EPA should be given the authority to continued regulating treated seeds as such.

USDA stands ready to assist EPA with any additional questions. Please let me know if you would like to discuss further.

Sincerely,

Sheryl H. Kunickis

Sheryl Kunickis, Ph.D.